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R.W. PHILLIPS: "Skinner's science of dental materials", 7th edition, 1973, chapter 10, pages 136,138,144, Saunders, Pa., US;

- (B) Proprietor: Feinmann, Bernard Paul Philippe 18 CH. William Barbey CH-1292 Chambery (CH)
- (7) Proprietor: Martignoni, Mario Via Maria Adelaide 5 Rome (IT)
- (I) Inventor: Feinmann, Bernard Paul Philippe 18 CH. William Barbey CH-1292 Chambery (CH) Inventor: Martignoni, Mario Via Maria Adelaide 5 Rome (IT)
- (N) Representative: Walbeoff, William John Dow Corning Limited Cardiff Road Barry South Glamorgan CF6 7YL Wales (GB)
- (3) References cited:
  JOURNAL OF CELLULAR PLASTICS, vol. 13,
  no. 1, January/February 1977, pages 82-67, C.L.
  LEE et al.: "New silicone RTV foam"
  C.J. BENNING: "Plastic foams: the physics and
  chemistry of product performance and process
  technology", vol. 1, 1969, pages 597-602, J.
  Wiley and Sons, New York, US;

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### Description

Background of the Invention

This invention relates to the treatment of dental patients using a foam material. The treatment includes retraction of gingival margins, cushioning dental appliances, cleaning of tooth surfaces and the dressing of wounds in the mouth.

1

Although dentistry is a technically advanced art there remain areas in need of improvement and problems which require solutions.

One such area is the retraction of the gingival margin in preparation for subsequent subgingival curettage or for the taking of dental impressions. The management of the gingival tissue prior to the taking of a precise impression for prosthetic laboratory work has been among the most difficult procedures in dentistry. The tissue next to the working site must be pushed away from the prepared borders and, if possible, reduced in size.

Many different materials and methods have been used for this work including electrosurgical trophying, the pressing in of restriction rings, copper tubes, retraction sleeves, gingitage (trophying with rotary diamond points), vascular-constrictor-containing retraction cords, astringent substances contained in retraction cords, vascular-constrictor and/or astringent-containing gels and pellets, and the like.

These methods and materials of the prior art have been successful to varying degrees in accomplishing the preparation of gingival tissue for subsequent procedures. However, most of these materials have accompanying disadvantages. For example, the prior art methods and materials may result in sulcus borders which are not complete and not smooth. In other cases there is a substantial risk of postoperative tissue loss with aesthetically unsatisfying results. In some cases continual bleeding of the gums makes it difficult to take impressions. There are often manual difficulties for the dentist in using some of the prior art materials and procedures. Other of the prior art methods result in increased cardiovascular risk and sometimes in severe and lasting postoperative pain.

There are other needs in the field of dentistry which have not been adequately met in the past and which would benefit from new materials and methods. Although toothbrushing and the use of dental floss have long been accepted as means for cleaning teeth and stimulating gums, it would be an improvement to find a material or method which provided improved cleaning of tooth surfaces, especially at intricate shapes and in close passages between teeth and/or fixed prosthetic parts.

There has also been a long-felt need in the dental profession for a cushion material to fit between dental appliances and irritated gums. Such a material, which promotes healing and is readily applicable by the wearer of the appliance, would be especially useful.

There has also been a long-felt need in the dental profession for a more practical wound

dressing which can be used in the mouth. Normal gauze and cloth bandages are not comfortably useful in a dental subject's mouth for long periods of time. Normal dental peridontal pressure packs become hard when wet so that they only protect the wound and do not apply a uniform pressure. Foam dressings, such as Dow Coming's SILAS-TIC® Foam Dressing, are known for use in open, granulating wounds. However, the system of components used to generate this foam dressing has a viscosity which, when first mixed, is not sufficiently high to be normally desirable in a respiratory pathway and the resulting foam composition is not sufficiently resistant to compression to meet the needs of dentistry described above. This prior art foam dressing also has the disadvantage of an unpleasant taste. Such prior art foams are described in greater detail in British patents 798,669 and 867,619.

It is known from British patent 841,815 to use a non-foaming silicone room temperature vulcanizing composition for making dental impressions.

It is known from US Patent No. 3,399,457 to use a rigid foam to form a permanently deformable bite block.

Summary of the Invention

It is, therefore, an object of this invention to obtain temporary separation of the gingival border from the adjacent tooth.

It is a further object of this invention to obtain improved cleaning of tooth surfaces. It is also an object of this invention to place a cushion between a dental appliance and the gum against which it is worn.

It is still another object of this invention to place a foam dressing in open wounds in the mouth.

It is also another object of this invention to place an improved pressure pack on dental wounds.

It is another object of this invention to present a foam composition for dental use having a desirable resistance to compression after foaming and a paste-like consistency before foaming.

It is also an object of this invention to overcome the disadvantages of the prior art.

These objects are accomplished by a biocompatible elastomeric foam-forming composition which is useful in dentistry. The foam is developed from a pastel-like system of components such that after a volume expansion of at least about 150%, a uniformly fine-grained foam material is obtained. The developed foam has a resistance to compression such that a pressure of at least about 50g per square cm (4905 Pa) applied against one side results in a 10% deflection of the material. In a preferred embodiment, such a pressure of about 80g per square cm (7848 Pa) results in a 10% deflection.

The paste-like consistency of the foam-forming composition and the resistance to compression of the resulting foam give this composition surprising and unexpected utility in dentistry over known materials, making new methods of treatment possible.

This foam-forming composition may be used in a process for temporarily separating the gingiva from the adjacent tooth in the mouth of a dental patient. The process includes the steps of placing the composition at the margin between the gingiva and the tooth, placing a carrier over the composition to contain the foam as it develops, maintaining the developed foam in pressure contact with the margin for a period of time, and removing the foam from contact with the margin.

Subsequent treatment of the tooth may be accomplished after the foam is removed such as gingival curettage or the taking of a dental impression.

When the foam is formed in contact with a tooth surface, it may be used in another aspect of the present invention to clean the tooth surface by causing relative motion between the tooth surface and the foam. Such relative motion may be accomplished by a chewing or swallowing motion made by the dental patient.

In yet another aspect of the present invention the foam-forming composition is placed on the surface of a dental appliance which is normally in contact with a dental patient's gums and the appliance is placed against the gum while the foam is developed from the system of components.

In still another aspect of the present invention the foam-forming composition is placed in a wound in the mouth of a dental patient and the foam is allowed to develop in the wound. The developed foam is maintained in the wound during healing.

The Drawings

The invention will now be described with reference to the accompanying drawings wherein

Fig. 1 shows the prior art method wherein the tooth is prepared down to the gingival sulcus by means of a rotating drill.

Figs. 2, 3 and 4 show the prior art method wherein retraction threads are used to separate the gingiva from the adjacent tooth.

Fig. 5 shows the present invention wherein foam is used to compress the sulcus and gingiva.

Fig. 6 shows the present invention wherein foam provides a cushion between a dental appliance and the gum.

Fig. 7 shows the present invention wherein a foam material is applied as a dressing to maintain a blood clot after extraction.

Fig. 8 shows the present invention wherein a carrier is being used to contain the development of a foam around the upper teeth and gums in the mouth of a dental patient.

Fig. 9 shows the present invention wherein a developed foam structure is used in cleaning the upper teeth or in separating the gum from the adjacent tooth as is shown in Fig. 5.

Fig. 10 shows the present invention used as a pressure pack during peridontal intervention.

**Detailed Description** 

Referring more specifically to Fig. 1 there is shown a prior art method of separating gingival margin 1 from dentin 2 during a procedure in which the surface 3 of the tooth prior to preparation is removed in preparation for subsequent capping with an artificial material.

Removal of surface 3 and the pushing back of ginglyal margin 1 is accomplished by means of cutting surface 4 which is controlled by drill shank

The prior art method, which is known as gingleage, has the disadvantage that it bruises margin 1, often causing it to bleed and swell, making the subsequent taking of good impressions difficult.

Referring more specifically to Figs. 2, 3 and 4 there is shown another prior art method of pushing back gingival marginl from dentin 2. As in Fig. 1, dentin 2 has had tooth surface 3 removed in preparation for subsequent capping.

Retraction threads 6 of various sizes are used to separate gingival margin 1 from dentin 2. Fig. 3. shows in enlarged cross-section threads 6, which may be impregnated with a vascular constrictive chemical being pressed into the space between the gingival margin 1 and dentin 2 with dental instrument 7. Fig. 4 shows in enlarged cross section the condition of threads 6 after being pressed into place by instrument 7. Fig. 4 also shows a tip portion 8 of margin 1 which is beginning to curl or "rebound" in the direction of tooth base 2. The extent of the rebound is shown by tip portion 8 in Fig. 2 after threads 6 have been removed. The rebound of tip portion 8 after retraction threads 6 have been removed is a problem of this prior art method in that it makes subsequent treatments, such as the taking of impressions, difficult.

Referring more specifically to Fig. 5 there is shown an embodiment of the present invention wherein foam material 9 has been formed over tooth 10 to separate tooth surface 11 from gingival margin 1. The foam is held against tooth 10 and margin 1 by a downward force as shown by the arrow. The force may be applied by, for example, an opposing tooth or by a dental instrument.

It can be seen in Fig. 5 that gingival margins 1 are uniformly compressed and separated from tooth surface 11. Surprisingly, it has been observed that margin 1 retains its compressed shape and its separation from tooth surface 11 for a period of time sufficient to enable subsequent procedures such as the cleaning of portion 12 of surface 11 which is normally covered by margin 1 or the taking of an impression of the tooth using a dental impression material. It is further observed that there is no "rebound" effect shown by the tip of the gingival margin and that there is no accompanying swelling or pain when the present invention is used. Cleaning portion 12 and the taking of impressions, both of which are facilitated by the present invention are procedures which will be well known to one of ordinary technical skill in the dental art and need not be

detailed here.

Foam 9 is developed from a system of components which, when mixed together and applied to the tooth and gum, will flow into the normal space between tooth surface 11 and margin 1 under only slight pressure applied by the dentist or by the dental patient. As the foam develops while being held in place by a suitable carrier, as is described in greater detail in connection with Fig. 8, the portion of the system of components which flowed between margin 1 and surface 11 creates a foam which presses margin 1 away from surface II.

Foam 9 is formed from a silicone material. To be useful the silicone material should be tissue compatible and non-toxic and the development of foam 9 from a system of components should not result in the evolution of a toxic or offensive gas.

Especially good results have been obtained using a silicone elastomer foam-forming composition which is made from a system of components comprising silicone fluids, siliceous fillers, a crosslinker, a source of hydrogen and a catalyst. In order to be useful in the present invention these components must be combined in relative ratios such that the combined system of components has a paste-like consistency and so that the resulting elastomeric foam has sufficient resistance to compression to be useful. The surprising and unexpected results which provide the technical advantage for the present elastomeric foam over the elastomeric foams of the prior art (such as the aforementioned Dow Corning SILASTIC® Foam Dressing) are believed to result from the relative ratios of the components.

For example said silicone elastomeric foamforming composition has been found to display a useful paste-like consistency and to display a useful resistance to compression in the developed foam only when its components are combined in certain ratios. Said silicone elastomeric foam is useful in the present invention when the system of components from which it is developed includes from about 190 to about 210 parts by weight of silicone fluids; from about 85 to about 110 parts by weight of a siliceous filler; from about 12 to about 16 parts by weight of a crosslinker; from about 18 to about 22 parts by weight of a hydrogen source, and from about 45 to about 55 parts by weight of a catalyst component. Optionally, the system of components may contain colorants and flavorings.

It has been observed that whenever the ratio of components varies from the above ratios in silicone elastomeric foam the usefulness of the material diminishes. Such a variance results in the system of components losing its paste-like consistency and in the developed foam having a resistance to compression which is not useful in the desired applications.

The resistance to compression of the foams employed in the present invention was measured by loading a force against the end of a foam cylinder measuring 2.5cm in length and 3.5cm in diameter. Loading was increased until a 10%

deflection occurred. Generally speaking, a 50g per square cm (4905 Pa) loading is required to cause such a deflection in foams useful in the present invention. For comparison, an identically shaped sample of a foam composition made from Dow Corning SILASTIC® Foam Dressing, which is not sufficiently resistant to be used in the present invention, required only 10g per square cm (981 Pa) to obtain a 10% deflection. Foams which require less than 50g per square cm (4905 Pa) to achieve a 10% deflection in this test have a diminished usefulness in the present invention. The presently preferred embodiment, described below, requires an 80g per square cm (7848 Pa) loading to achieve a 10% deflection in this test.

In order to be useful in this invention, a minimum expansion of about 150% is required of a foam material in addition to the resistance to compression described above. The expansion, in combination with the resistance, apparently enables the elastomeric foam to act as is described in Figs. 5-10. The volume expansion of foams is readily measured by placing the system of components in a graduated cylinder and calculating the volume of the starting material against the volume of the finished foam.

Foams, which show greater volume expansion than 150% but do not develop the necessary resistance to compression, are not useful in the present invention.

Another aspect in which the above-described silicone elastomeric foam demonstrates a surprising and unexpected technical advance over the prior art is in the mixing and curing time. For example, the preferred embodiment, described below, provides a curing time of about four minutes between mixing and curing which gives the dental practitioner an appropriate time to position the system of components after mixing.

A preferred embodiment of the abovedescribed silicone elastomeric foam is made from a system of components which comprises a first component formed from 95 to 105 parts by weight of a -OH terminated polydimethylsiloxane polymer; from 52 to 63 parts by weight of a siliceous filler, from 9 to 11 parts by weight of an -SiH functional silicone fluid, from 9 to 11 parts by weight of a low-viscosity hydroxyfunctional polydimethylsiloxane fluid; from 9 to 11 parts by weight of diphenylmethylsilanol; from 3 to 5 parts by weight of normal propylorthosilicate, and from 7-9 parts by weight of a white pigment. The second component is formed from 95 to 105 parts by weight of a trimethyl terminated polydimethyl siloxane fluid having a viscosity of about 12,500 centistokes (1.25 x 10<sup>-2</sup> m<sup>2</sup>/s); from about 35 to about 45 parts by weight of a siliceous filler; from about 45 to about 55 parts by weight stannous octoate; from about 1.5 to about 2.5 parts by weight of a pink pigment, and from about O.I to about 0.2 parts by weight of a flavoring.

The first and second components are prepared separately and stored in tubes. The orifices of the tubes are adjusted in size so that equal length strips of the first and second components may be

20

extruded onto a mixing surface while maintaining the correct relative ratio of components. The strips are then combined, as by a spatula, and immediately placed into position for foam development.

In the preferred embodiment the colored pigment is placed only in one component. The dental practitioner or patient may then understand from a uniformly colored mixture that the components are evenly dispersed. Uniform blending of the two components is important to obtain a uniformly textured foam composition.

Referring more specifically to Fig. 6 there is shown dental appliance 13 mounted on gum 14 and having foam material 9 acting as a cushion therebetween. In this embodiment of the invention, foam material 9 is formed by first placing the foam-forming composition onto the side of appliance 13 which would normally contact gum 14. Appliance 13 is then mounted on gum 14 while foam 9 is allowed to develop. This application of the present invention is especially suitable when gum 14 is sore or irritated.

Referring more specifically to Fig. 7 there is shown mouth 15 of a dental subject having open wound 16 resulting from an extraction on the lower jaw. Syringe 17 Is being used to place the foam-forming composition 18 in an extraction wound 16. Composition 18 has a paste-like consistency which enables it to fill the shape of open wound 16 without danger of flowing into respiratory passageway 19 of the dental patient. The composition 18, when it cures to an elastomeric foam material, will act as a dressing and will also keep the normal extraction blood clot in place to prevent the "dry socket" condition which results whenever an extraction blood clot comes out of place.

It has been observed that composition 18 develops into a foam material which operates as a wound dressing to promote healing. The wound is maintained in a clean condition, protected from direct contact with the atmosphere or the mouth while the porous nature of the foam draws secretions away from the wound.

The foam wound dressing has the added advantage that it can be removed, cleaned and replaced by the dental subject. As the wound heals and changes shape subsequent foam dressings may be applied by the patient without the intervention of a dental professional.

Syringe 17 is shown as a convenient device for applying composition 18 to locations in the back of the mouth. Alternatively, composition 18 could be applied by means of a dental spatula after the base component and the catalyst component had first been mixed together on a palette.

Referring more specifically to Fig. 8, there is shown mouth 15 of a dental patient in which carrier 20 is being held in place by finger 21 while a foam-forming composition on carrier 20 develops into a foam while being held against the dental subject's upper teeth and gums.

Carrier 20 may be of any useful size or shape and can be made of any suitable material to

contain the foam-forming composition against the desired surface in mouth 15. For example, a dental instrument may be used for small locations or a spoon can be used.

Referring more specifically to Fig. 9 there is shown mouth 15 of a dental subject with foam material 9 covering the upper teeth and gums. Foam material 9 of Fig. 9 is of the shape which would have been produced by carrier 20 of Fig. 8.

Foam material 9 of Fig. 9 may be held in place under pressure by lower jaw and teeth 22 for a time sufficient to accomplish the separation of the gingivel margin from the tooth surface as is shown in Fig. 5. Experience has shown that such separation can be accomplished by meintaining said pressure for a period of from about 5 to about 10 minutes for the average dental patient. Foam material 9 is then removed to facilitate subsequent procedures.

Alternatively the foam material 9 of Fig. 9 may be moved relative to the surface of the teeth with which it is in contact to accomplish cleaning of said surface. Only small, repeated relative movements are necessary. Such movements can be accomplished by manual manipulation of the foam or, as is shown in Fig. 9 by the arrows, by a chewing action of the lower jaw and teeth 22 against foam material 9.

Referring more specifically to Fig. 10 there is shown a portion 23 of the lower teeth and jaws of a dental patient wherein wound 25 is present resulting, for example, from a tissue grafting procedure. Elastomeric foam composition 24 is shown in use as a pressure pack on wound 25.

Pressure pack 24 is applied by placing the foam forming composition in contact with wound 25. Upon curing to an elastomer the pressure pack is held against wound 25 by the pressure of the patient's lip. Unlike the pressure packs of the prior art, pressure pack 24 remains resilient even when wet and distributes pressure uniformly against wound 25. Pressure pack 24 can be removed, cleaned and reinserted and can be replaced, if necessary, by a new foam structure if the shape of the wound changes significantly.

The present invention has been disclosed in the above teachings and drawings with sufficient clarity and conciseness to enable one skilled in the art to make and use the invention, to know the best mode for carrying out the invention and to distinguish it from other inventions and from what is old. Many variations and obvious adaptations of the invention will readily come to mind, and these are intended to be contained within the scope of the invention as claimed below.

## Claims

1. A paste-like, biocompatible, silicone, elastomeric foam-forming composition for use in a dental procedure comprising temporarily separating the gingiva from the adjacent tooth in the mouth of a dental patient, the said composition exhibiting a volume expansion of at least 150% during the foam-forming process to provide a

uniform foam having a resistance to compression such that a pressure of at least 50g per square centimetre (4905 Pa) is required to produce a 10% deflection of the foam, and said foam-forming composition comprising from about 190 to about 210 parts by weight of silicone fluids, from about 85 to about 110 parts by weight of a siliceous filler, from about 12 to about 16 parts by weight of a crosslinker, from about 18 to about 22 parts by weight of a hydrogen source and from about 45 to about 55 parts by weight of a catalyst component.

2. A composition as claimed in Claim 1 wherein the dental procedure comprises placing the foam forming composition in contact with the margin between the gingive and the adjacent tooth, allowing the composition to foam and subsequently removing the foam.

3. A composition as claimed in Claim 1 or Claim 2 wherein the foam forming composition is supported by a carrier therefor during the foam-

forming process.

4. A composition as claimed in any one of the preceding claims wherein the dental procedure includes the steps of placing the composition at the margin between the gingiva and the adjacent tooth, placing a carrier over the composition to contain the foam as it develops, maintaining the developed foam in pressure contact with the margin for a period of time and removing the foam from contact with the margin.

5. A composition as claimed in any one of Claims 1 to 4 wherein the procedure includes an additional subsequent step which is enhanced by the temporary separation of the gingive from the

tooth.

6. A composition as claimed in Claim 5 wherein said additional step comprises taking a dental

impression of at least said margin.

7. A paste-like biocompatible, silicone, elastomeric foam-forming composition for use in a process for cleaning the surface of a tooth or of a dental appliance which comprises the steps of (a) placing the components of the system around at least one tooth or appliance of a dental patient; (b) placing a carrier over the components, the carrier being of a shape and size sufficient to contain the foam composition as it is developed by the system of components so that said foam develops in contact with said tooth or appliance; and subsequently (c) moving said foam composition and said tooth or appliance relative to each other, said foam-forming composition exhibiting a volume expansion of at least 150% during the foam-forming process to provide a uniform foam having a resistance to compression such that a pressure of at least 50g per square centimetre (4905 Pa) is required to produce a 10% deflection of the foam and said foam-forming composition comprising from about 190 to about 210 parts by weight of silicone fluids, from about 85 to about 110 parts by weight of a siliceous filler, from about 12 to about 16 parts by weight of a crosslinker, from about 18 to about 22 parts by weight of a hydrogen source and from about 45 to about 55 parts by weight of a catalyst component.

8. A paste-like, biocompatible, silicone, elastomeric foam-forming composition for use in a method for forming a foam cushion between the gums of a dental patient and a dental appliance, said method comprising (a) placing the composition on the surface of the appliance which is normally in contact with the gum of said patient, and (b) placing the appliance against the gum while the foam is developed from the system; said foam-forming composition exhibiting a volume expansion of at least 150% during the foam-forming process to provide a uniform foam having a resistance to compression such that a pressure of at least 50g per square centimetre (4905 Pa) is required to produce a 10% deflection of the foam, and said foam-forming composition comprising from about 190 to about 210 parts by weight of silicone fluids, from about 85 to about 110 parts by weight of a siliceous filler, from about 12 to about 16 parts by weight of a crosslinker, from about 18 to about 22 parts by weight of a hydrogen source and from about 45 to about 55 parts by weight of a catalyst component.

9. A paste-like, biocompatible silicone, elastomeric foam-forming composition for use in a method of producing a foam dressing in a wound in the mouth of a dental patient, the method comprising: (a) placing the composition in contact with the wound, (b) allowing the foam to develop and (c) maintaining the foam in contact with the wound during healing; said foam-forming composition exhibiting a volume expansion of at least 150% during the foam-forming process to provide a uniform foam having a resistance to compression such that a pressure of at least 50g per square centimetre (4905 Pa) is required to produce a 10% deflection of the foam, and said foam-forming composition comprising from about 190 to about 210 parts by weight of silicone fluids, from about 85 to about 110 parts by weight of a siliceous filler, from about 12 to about 16 parts by weight of a crosslinker, from about 18 to about 22 parts by weight of a hydrogen source and from about 45 to about 55 parts by weight of

a catalyst component.

10. A method of making a dental prosthesis which includes the steps of contacting the margin between the gingiva and an adjacent tooth with a paste-like, biocompatible, silicone, elastomeric foam-forming composition, allowing the foam to develop, maintaining the developed foam in pressure contact with the margin for a period of time, removing the developed foam from the margin and thereafter applying to at least the margin a dental impression material; said foemforming composition exhibiting a volume expansion of at least 150% during the foam-forming process to provide a uniform foam having a resistance to compression such that a pressure of at least 50g (4905 Pa) per square centimetre is required to produce a 10% deflection of the foam, and said foam-forming composition comprising from about 190 to about 210 parts by weight of silicone fluids, from about 85 to about 110 parts by weight of a siliceous filler, from about 12 to

35

about 16 parts by weight of a crosslinker, from about 18 to about 22 parts by weight of a hydrogen source and from about 45 to about 55 parts by weight of a catalyst component.

### Patentansprüche

1. Pastenartige, bioverträgliche und einen elastomeren Siliconschaum bildende Masse zur Verwendung bei einer Zahnbehandlung, bei welcher das Zahnfleisch temporär vom benachbarten Zahn im Mund eines Patienten entfernt wird, dadurch gekennzeichnet, daß diese Masse eine Volumenexpansion von wenigstens 150 % während des Aufschäumungsprozesses aufweist und hierbei einen gleichförmigen Schaum mit einer solchen Kompressionsfestigkeit ergibt, daß ein Druck von wenigstens 50 g/cm<sup>2</sup> (4 905 Pa) zur Erzeugung einer Biegung des Schaums von 10 % erforderlich ist, und daß diese schaumbildende Masse etwa 190 bis etwa 210 Gewichtsteile flûssige Silicone, etwa 85 bis etwa 110 Gewichtstelle eines siliciumhaltigen Füllstoffes, etwa 12 bis etwa 16 Gewichtsteile eines Vernetzungsmittels, etwa 18 bis etwa 22 Gewichtstelle einer Wasserstoffquelle und etwa 45 bis etwa 55 Gewichtsteile einer Katalysatorkomponente enthält.

2. Masse nach Anspruch 1, dadurch gekennzeichnet, daß die Zehnbehandlung derin besteht, daß man die schaumbildende Masse in den Spalt zwischen dem Zehnfleisch und dem benachbarten Zahn einbringt, die Masse aufschäumen läßt und den Schaum dann entnimmt.

3. Masse nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß man die schaumbildende Masse während des Aufschäumens mit einem Träger stützt.

4. Masse nach irgendeinem der vorhergehenden Ansprüche, dadurch gekennzeichnet, daß die Zahnbehandlung darin besteht, daß man die schaumbildende Masse in den Spalt zwischen dem Zahnfleisch und dem benachbarten Zahn einbringt, auf die Masse einen den Schaum während seiner Entwicklung umfassenden Träger aufbringt, den entwickelten Schaum während einer ausreichenden Zeit mit dem Spalt in Druckkontakt hält und den Schaum dann entnimmt.

5. Masse nach irgendeinem der Ansprüche 1 bis 4, dadurch gekennzeichnet, daß die Zahnbehandlung in einer weiteren anschließenden Stufe besteht, bei welcher das Zahnfleisch temporär vom Zahn abgetrennt wird.

6. Masse nach Anspruch 5, dadurch gekennzeichnet, daß die weitere Stufe darin besteht, daß man wenigstens vom Spalt einen Zahnabdruck macht.

7. Pastenartige, bloverträgliche und einen elastomeren Siliconschaum bildende Masse zur Verwendung bei einem Verfahren zur Reinigung der Oberfläche eines Zahns oder einer Dentalvorrichtung, wobei (a) die Komponenten des Systems um wenigstens einen Zahn oder eine Vorrichtung eines Patienten angeordnet werden, (b) über den Komponenten ein Träger angeordnet wird, der eine solche Form und Größe aufweist, daß er die

Schaumzusammensetzung während ihrer Entwicklung durch das Komponentensystem so umfaßt, daß sich der Schaum im Kontakt mit dem Zahn oder der Vorrichtung entwickelt, und (c) die Schaumzusammensetzung und der Zahn oder die Vorrichtung relativ zueinander bewegt werden, dadurch gekennzeichnet, daß die schaumblidende Masse eine Volumenexpansion von wenigstens 150% während des Aufschäumungsprozesses aufweist und hierbei einen gleichförmigen Schaum mit einer solchen Kompressionsfestigkeit ergibt, daß ein Druck von wenigstens 50 g/ cm<sup>2</sup> (4 905 Pa) zur Erzeugung einer Biegung des Schaums von 10 % erforderlich ist, und daß diese schaumbildende Masse etwa 190 bis etwa 210 Gewichtsteile flüssige Silicone, etwa 85 bis etwa 110 Gewichtsteile eines siliciumhaltigen Füllstoffes, etwa 12 bis etwa 16 Gewichtstelle eines Vernetzungsmittels, etwa 18 bis etwa 22 Gewichtsteile einer Wasserstoffquelle und etwa 45 bis 55 Gewichtsteile einer Katalysatorkomponente enthält.

8. Pastenartige, bioverträgliche und einen elastomeren Siliconschaum bildende Masse zur Verwendung bei einem Verfahren zur Bildung eines Schaumkissens zwischen dem Gaumen eines Patienten und einer Dentalvorrichtung, wobei (a) die Masse auf der Oberfläche der Vorrichtung, die sich gewöhnlich im Kontakt mit dem Gaumen des Patienten befindet, angeordnet wird und (b) die Vorrichtung während der Entwicklung des Schaums aus dem System gegen den Gaumen gedrückt wird, dadurch gekennzeichnet, daß die schaumbildende Masse eine Volumenexpansion von wenigstens 150% während des Aufschäumungsprozesses aufweist und hierbei einen gleichförmigen Schaum mit einer solchen Kompressionsfestigkeit ergibt, daß ein Druck von wenigstens 50 g/cm<sup>2</sup> (4 905 Pa) zur Erzeugung einer Biegung des Schaums von 10 % erforderlich ist, und daß diese schaumbildende Masse etwa 190 bis etwa 210 Gewichtsteile flüssige Silicone. etwa 85 bis etwa 110 Gewichtsteile eines siliciumhaltigen Füllstoffes, etwa 12 bis etwa 16 Gewichtsteile eines Vernetzungsmittels, etwa 18 bis etwa 22 Gewichtsteile einer Wasserstoffquelle und etwa 45 bis 55 Gewichtsteile einer Katalysatorkomponente enthält.

9. Pastenartige, bioverträgliche und einen elastomeren Siliconschaum bildende Masse zur Verwendung bei einem Verfahren zur Bildung eines Schaumverbands in einer Wunde im Mund eines Patienten, wobei (a) die Masse mit der Wunde in Kontakt gebracht wird, (b) der Schaum sich entwickeln gelassen wird und (c) der Schaum während des Heilens mit der Wunde in Kontakt belassen wird, dadurch gekennzeichnet, daß die schaumbildende Masse eine Volumenexpansion von wenigstens 150% während des Aufschäumungsprozesses aufweist und hierbei einen gleichförmigen Schaum mit einer solchen Kompressionsfestigkeit ergibt, daß ein Druck von wenigstens 50 g/cm2 (4 905 Pa) zur Erzeugung einer Biegung des Schaums von 10 % erforderlich ist, und daß diese schaumbildende Masse etwa 190 bis etwa 210 Gewichtsteile flüssige Silicone, etwa 85 bis etwa 110 Gewichtsteile eines silicium-haltigen Füllstoffes, atwa 12 bis etwa 16 Gewichtsteile eines Vernetzungsmittels, etwa 18 bis etwa 22 Gewichtsteile einer Wasserstoffquelle und etwa 45 bis 55 Gewichtsteile einer Katalysatorkomponente enthält.

10. Verfahren zur Herstellung einer Dentalprothese, wobei eine pastenartige, bioverträgliche und einen elastomeren Siliconschaum bildende Masse in den Spalt zwischen dem Zahnfleisch und dem benachbarten Zahn eingebracht wird, der Schaum sich entwickeln gelassen wird, der entwickelte Schaum während einer ausreichenden Zeitdauer mit dem Spalt in Druckkontakt gehalten wird, der entwickelte Schaum aus dem Spalt genommen wird und dann wenigstens in den Spalt ein Zahnabdruckmaterial eingebracht wird, dadurch gekennzeichnet, daß die schaumbildende Masse eine Volumenexpansion von wenigstens 150% während des Aufschäumungsprozesses aufweist und hierbei einen gleichförmigen Schaum mit einer solchen Kompressionsfestigkeit ergibt, daß ein Druck von wenigstens 50 g/cm² (4 905 Pa) zur Erzeugung einer Biegung des Schaums von 10 % erforderlich ist, und daß diese schaumbildende Masse etwa 190 bis etwa 210 Gewichtsteile flüssige Silicone, etwa 85 bis etwa 110 Gewichtsteile eines siliciumhaltigen Füllstoffes, etwa 12 bis etwa 16 Gewichtsteile eines Vernetzungsmittels, etwa 18 bis etwa 22 Gewichtsteile einer Wasserstoffquelle und etwa 45 bis 55 Gewichtsteile einer Katalysatorkomponente enthält.

# Revendications

1. Une composition biocompatible pâteuse aux silicones, formatrice de mousse élastomère, à utiliser dans une intervention dentaire impliquant de séparer temporairement la gencive de la dent adjacente dans la cavité buccale d'un patient. ladite composition présentant une expansion de volume d'au moins 150 % pendant le processus de formation de mousse en produisant une mousse uniforme dont la résistance à la compression est telle qu'il faut une pression d'au moins 50 g par centimètre carré (4905 Pa) pour provoquer une déformation de 10 % de la mousse, et ladite composition formatrice de mousse comprenant environ 190 à environ 210 parties en poids de fluides de silicone, environ 85 à environ 110 parties en poids d'une charge siliceuse, environ 12 à environ 16 parties en poids d'un agent de réticulation, environ 18 à environ 22 parties en poids d'une source d'hydrogène et environ 45 à environ 55 parties en poids d'un composant catalytique.

2. Une composition telle que revendiquée dans la revendication 1, dans laquelle l'intervention dentaire implique de placer la composition formatrice de mousse en contact avec la marge comprise entre la gencive et la dent adjacente, de laisser la composition mousser et de retirer ensuite la mousse.

3. Une composition telle que revendiquée dans la revendication 1 ou la revendication 2, dans laquelle la composition formatrice de mousse est supportée par un support prévu à cet effet pendant le processus de formation de la mousse.

4. Une composition telle que revendiquée dans l'une quelconque des revendications précédentes, dans laquelle l'intervention dentaire comprend les étapes qui consistent à placer la composition au niveau de la marge comprise entre la gencive et la dent adjacente, à placer un support par dessus la composition pour contenir la mousse tandis qu'elle se développe, à maintenir la mousse développée en contact sous pression avec la marge pendant une certaine période de temps et à mettre la mousse hors du contact de la marge.

5. Une composition telle que revendiquée dans l'une quelconque des revendications 1 à 4, dans laquelle l'intervention comprend une étape supplémentaire subséquente qui est favorisée par le fait que la gencive est temporairement séparée de la dent.

6. Une composition telle que revendiquée dans la revendication 5, dans laquelle ladite étape supplémentaire consiste à prendre une empreinte

d'au moins ladite marge.

7. Une composition blocompatible pâteuse aux silicones, formatrice de mousse élastomère, à utiliser dans un procédé pour nettoyer la surface d'une dent ou d'une prothèse dentaire qui comprend les étapes consistant à (a) placer les composants du système autour d'au moins une dent ou prothèse d'un patient, (b) placer un support par dessus les composants, la forme et la taille du support étant suffisantes pour contenir la composition de mousse tandis qu'elle est développée par le système de composants de facon que ladite mousse se développe au contact de ladite dent ou prothèse, et ensuite (c) déplacer ladite composition de mousse et ladite dent ou prothèse l'une par rapport à l'autre, ladite composition formatrice de mousse présentant une expansion de volume d'au moins 150 % pendant le processus de formation de mousse en produisant une mousse uniforme dont la résistance à la compression est telle qu'il faut une pression d'au moins 50 g par centimètre carré (4905 Pa) pour provoquer une déformation de 10 % de la mousse, et ladite composition formatrice de mousse comprenant environ 190 à environ 210 parties en poids de fluides de silicone, environ 85 à environ 110 parties en poids d'une charge siliceuse, environ 12 à environ 16 parties en poids d'un agent de réticulation, environ 18 à environ 22 parties en poids d'une source d'hydrogène et environ 45 à environ 55 parties en poids d'un composant

8. Une composition blocompatible pâteuse aux silicones, formatrice de mousse élastomère, à utiliser dans un procédé pour former un coussin de mousse entre la gencive d'un patient et une prothese dentaire, ledit procédé impliquant (a) de placer la composition sur la surface de la prothèse qui se trouve normalement au contact de la

gencive dudit patient et (b) de placer la prothèse contre la gencive tandis que la mousse est développée par le système, ladite composition formatrice de mousse présentant une expansion de volume d'au moins 150 % pendant le processus de formation de mousse en produisant une mousse uniforme dont la résistance à la compression est telle qu'il faut une pression d'au moins 50 g par centimètre carré (4905 Pa) pour provoquer une déformation de 10 % de la mousse, et ladite composition formatrice de mousse comprenant environ 190 à environ 210 parties en poids de fluides de silicone, environ 85 à environ 110 parties en poids d'une charge, siliceuse, environ 12 à environ 16 parties en poids d'un agent de réticulation, environ 18 à environ 22 parties en poids d'une source d'hydrogène et environ 45 à environ 55 parties en poids d'un composant catalytique.

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9. Une composition biocompatible pâteuse aux silicones, formatrice de mousse élastomère, à utiliser dans un procédé pour produire un pansement de mousse dans une plaie de la cavité buccale d'un patient, le procédé impliquant: (a) de placer la composition au contact de la plaie, (b) de laisser la mousse se développer et (c) de maintenir la mousse au contact de la plaie durant la cicatrisation; ladite composition formatrice de mousse présentant une expansion de volume d'au moins 150 % pendant le processus de formation de mousse en produisant une mousse uniforme dont la résistance à la compression est telle qu'il faut une pression d'au moins 50 g par centimètre carré (4905 Pa) pour provoquer une déformation de 10 % de la mousse, et ladite composition formatrice de mousse comprenant environ 190 à environ 210 parties en poids de fluides de silicone, environ 85 à environ 110 parties en poids d'une charge siliceuse, environ 12 à environ 16 parties en poids d'un agent de réticulation, environ 18 à environ 22 parties en poids d'une source d'hydrogène et environ 45 à environ 55 parties en poids d'un composant catalytique.

10. Un procédé pour fabriquer une prothèse dentaire qui comprend les étapes consistant à mettre la marge comprise entre la gencive et une dent adjacente en contact avec une composition biocompatible pâteuse aux silicones, formatrice de mousse élastomère, à laisser la mousse se développer, à maintenir la mousse développée en contact sous pression avec la marge pendant une certaine période de temps, à retirer la mousse développée de la marge et à appliquer ensuite au moins à la marge une matière de prise d'empreintes dentaires; ladite composition formatrice de mousse présentant une expansion de volume d'au moins 150 % pendant le processus de formation de mousse en produisant une mousse uniforme dont la résistance à la compression est telle qu'il faut une pression d'au moins 50 g par centimètre carré (4905 Pa) pour provoquer une déformation de 10 % de la mousse, et ladite composition formatrice de mousse comprenant environ 190 à environ 210 parties en poids de fluides de silicone, environ 85 à environ 110 parties en poids d'une charge siliceuse, environ 12 à environ 16 parties en poids d'un agent de réticulation, environ 18 à environ 22 parties en poids d'une source d'hydrogène et environ 45 à environ 55 parties en poids d'un composant catalytique.

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